

**NIGHTTIME SLEEP-AID- diphenhydramine hcl capsule, liquid filled
BIONPHARMA INC.**

Diphenhydramine HCl 50mg, A+ Health, Made in India

Active ingredient (in each capsule)

Diphenhydramine HCl 50 mg

Purpose

Nighttime sleep-aid

Uses

- For relief of occasional sleeplessness
- reduces time to fall asleep if you have difficulty falling asleep

Warnings

Do not use

- for children under 12 years of age
- with any product containing diphenhydramine, even one used on skin.

Ask a doctor before use if you have

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland

Ask a doctor or pharmacist before use

if you are taking sedatives or tranquilizers.

When using this product

- avoid alcoholic beverages
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

sleeplessness persists continuously for more than 2 weeks, consult your doctor.

Insomnia may be a symptom of serious underlying medical illness.

If pregnant or breast- feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Centre right away.

Directions

- **Adults and children 12 years of age and over:** One softgel (50 mg) at bedtime if needed, or as directed by a doctor.
- swallow whole; do not crush, chew, or dissolve

Other information

- store at 20 °C to 25 °C (68 °F to 77 °F)
- avoid high humidity and excessive heat above 40 °C (104 °F).
- protect from light

Inactive ingredients

FD&C blue #1, gelatin, glycerin, polyethylene glycol 400, polyethylene glycol 600, propylene glycol, purified water, sorbitol sorbitan solution

Questions or comments?

1-888-235-2466(Mon-Fri 9AM-5PM EST)

DO NOT USE IF TAMPER-EVIDENT SEAL UNDER BOTTLE CAP IMPRINTED WITH “SEALED for YOUR PROTECTION” IS BROKEN OR MISSING.

This product is not manufactured or distributed by the owners of Unisom[®] SleepGels[®].

Manufactured for:

Bionpharma Inc.

Princeton, NJ 08540

Made in India

L0000778

R0124

Mfg. Lic. No.: TN00002123

2620515

Lot No.:

Exp. Date:

160's count

Compare to the active ingredient in Unisom® SleepGels®

NDC 69452-427-79

a+ health

maximum strength

nighttime

sleep-aid

diphenhydramine HCl capsules USP, 50 mg

fall asleep fast

sleep soundly

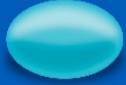


safe, non-habit

forming

one softgel per dose

160 softgels**

**liquid-filled capsules

<p>[†]Compare to the active ingredient in Unisom® SleepGels® NDC 69452-427-79</p> <p>a+health™ maximum strength nighttime sleep-aid diphenhydramine HCl capsules USP, 50 mg</p> <p> 160 softgels** **liquid-filled capsules</p> <p>one softgel per dose</p> <p>• fall asleep fast • sleep soundly • safe, non-habit forming</p>	<p>DO NOT USE IF TAMPER-EVIDENT SEAL UNDER BOTTLE CAP IMPRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING.</p>	<p>Drug Facts</p> <p>Active ingredient (in each capsule) Diphenhydramine HCl USP 50 mg..... Nighttime sleep-aid</p> <p>Uses</p> <ul style="list-style-type: none">■ for relief of occasional sleeplessness■ reduces time to fall asleep if you have difficulty falling asleep <p>Warnings</p> <p>Do not use</p> <ul style="list-style-type: none">■ for children under 12 years of age■ with any other product containing diphenhydramine, even one used on skin. <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none">■ glaucoma■ a breathing problem such as emphysema or chronic bronchitis■ difficulty in urination due to enlargement of the prostate gland <p>Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.</p> <p>When using this product</p> <ul style="list-style-type: none">■ avoid alcoholic beverages■ be careful when driving a motor vehicle or operating machinery <p>Stop use and ask a doctor if sleeplessness persists continuously for more than 2 weeks, consult your doctor. Insomnia may be a symptom of serious underlying medical illness.</p>	<p> N 3 69452 32279 6</p> <p>Manufactured for: Bionpharma Inc. Princeton, NJ 08540</p> <p>Made in India</p> <p>L0000778 R0124</p> <p>Mfg. Lic. No.: TN00002123 2620515</p> <p>Lot No.: Exp. Date:</p> <p>NVZ (23.8 x 14.9mm)</p> <p></p>

T00150R0124

NVZ
(60 x 25.4mm)

Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Centre right away.

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NIGHTTIME SLEEP-AID

diphenhydramine hcl capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69452-427
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
SORBITAN (UNII: 6O92ICV9RU)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	blue	Score	no score
Shape	OVAL	Size	13mm
Flavor		Imprint Code	B50
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69452-427-79	160 in 1 BOTTLE; Type 0: Not a Combination Product	03/21/2024	
2	NDC:69452-427-17	60 in 1 BOTTLE; Type 0: Not a Combination Product	03/21/2024	
3	NDC:69452-427-10	32 in 1 BOTTLE; Type 0: Not a Combination Product	03/21/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M010	03/21/2024	

Labeler - BIONPHARMA INC. (079637826)

Registrant - Bionpharma Inc. (079637826)

Establishment

Name	Address	ID/FEI	Business Operations
SOFTGEL HEALTHCARE PRIVATE LIMITED		675584180	manufacture(69452-427)

Revised: 3/2024

BIONPHARMA INC.